

**Remarks**

Claims 1-15 are currently pending and stand rejected.

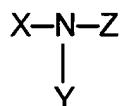
**Double Patenting Rejections and §102(e) Rejections Over Applicant's Prior Patents**

The Examiner has entered a rejection on the grounds of anticipation and/or obviousness under 35 U.S.C. §102(e) and obviousness-type double patenting over U.S. Patent No. 6,743,433, which claims a composition and method for treatment of acne using alkanolamines. U.S. Patent No. 6,743,433 was granted on application serial no. 10/085,864, the parent to this application and to which rights are claimed under 35 U.S.C. §120. In response to this rejection, a Terminal Disclaimer is submitted herewith, which should overcome the double patenting rejection. As the cited patent is the parent to this application, it should not be cited as prior art under 35 U.S.C. §102(e) and the rejection on the basis of anticipation and/or obviousness should be withdrawn. Accordingly, it is submitted that the rejections over U.S. Patent No. 6,743,433 should be withdrawn.

The Examiner has entered a rejection on the grounds of anticipation and/or obviousness under 35 U.S.C. §102(e), and obviousness-type double patenting, over U.S. Patent No. 6,365,623 ("the '623 Patent") which claims a method for reducing and preventing acneiform scars and reducing pore size comprising topically applying to affected skin areas a composition containing lipoic acid or a lipoic acid derivative in a dermatologically acceptable carrier, as recited in claim 1. None of the claims are directed to the combination of alkanolamines, tyrosine, and a sulfur ingredient as is required by all claims of the present application. (See claim 1 of the '623 Patent.) While the '623 Patent at claim 4, depending from claim 1, does claim active ingredients of lipoic acid or lipoic acid derivative (one potential sulfur ingredient) plus an adjunct ingredient of "an alpha-hydroxy acid ingredient, tyrosine, or mixtures thereof," the alkanolamine requirement is missing. While the '623 Patent at claim 11, depending

from claim 1, does claim active ingredients of lipoic acid or lipoic acid derivative plus an adjunct ingredient of “an aminoalcohol ingredient” (alkanolamines), and further reciting “wherein the aminoalcohol is dimethylaminoethanol” (claim 12 depending from claim 11), the tyrosine requirement is missing. No claims of the ‘623 patent overlap with any of the claims of the present application requiring the specific combination of:

- an alkanolamine of the formula:



wherein X, Y and Z are selected from the group consisting of hydrogen, C<sub>1</sub>-C<sub>3</sub> alkyl groups, C<sub>2</sub>-C<sub>4</sub> alkanol group, wherein at least one of X, Y, or Z is a C<sub>2</sub>-C<sub>4</sub> alkanol group bearing at least one hydroxyl group and optionally at least one carboxyl group;

- tyrosine; and
- a sulfur ingredient.

Further, the specification of the ‘623 patent merely includes aminoalcohols and tyrosine within a laundry list of possible *adjunct* ingredients to its *one required active ingredient of lipoic acid*. Neither the claims nor the disclosure of the patent involve the applicant’s specific combination of three active ingredients of alkanolamines, tyrosine, and a sulfur ingredient. It is respectfully submitted that the 35 U.S.C. §102(e) anticipation and double patenting rejections are in error because of the complete absence of the combination of alkanolamines, tyrosine and a sulfur ingredient in any of the patent claims, and that the rejection should be withdrawn.

In summary, it is respectfully submitted that the cited U.S. Patent No. 6,365,623 is for a separate and distinct invention than claimed in the present application, and the presently claimed invention is not obvious in view of this prior patent. The anticipation,

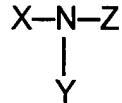
obviousness, and double patenting rejections over this patent is improper and should be withdrawn.

Rejections under 35 U.S.C. §102 (e) Over Other Art

In the Office Action dated March 24, 2005, the Examiner rejected claims 1-15 under 35 U.S.C. §102(e), as being anticipated by, or alternatively obvious over U.S. Patent No. 6,444,195 to Cole ("the '195 patent"), U.S. Patent No. 6,482,446 to Watson ("the '446 patent") or U.S. Patent No. 6,372,791 to (the '791 patent").

Applicant respectfully disagrees that the neither of these references, alone or in combination, discloses or suggests all elements of at least Applicant's claim 1. Specifically, all claims of Applicant's present invention require the **specific combination of**:

- **an alkanolamine** (of the formula:



wherein X, Y and Z are selected from the group consisting of hydrogen, C<sub>1</sub>-C<sub>3</sub> alkyl groups, C<sub>2</sub>-C<sub>4</sub> alkanol group, wherein at least one of X, Y, or Z is a C<sub>2</sub>-C<sub>4</sub> alkanol group bearing at least one hydroxyl group and optionally at least one carboxyl group);

- **tyrosine**; and
- **a sulfur ingredient.** (See Applicant's claim 1.)

The '195 Patent

The Examiner has cited the '195 patent (in rejecting Applicant's respective claims) for teaching acne-treating agents comprising alkanoalimine, lipoic acid, and

tyrosine, (Applicant claim 1 elements) as well as and hydroxyl acids, ascorbic acid derivatives retinoic acid derivatives, salicylic acid and that said aforementioned agents are present in amounts of .001-20% (all cited against elements within various dependent claims).

The '195 patent is directed to sunscreens containing dibenzoylmethane derivative, one of the most commonly used UV-A absorbers (to block UV-A radiation from reaching the skin, preventing sunburn, wrinkles, skin cancer and other sun damage to skin). (See col. 1, lines 10-15, 20-23) However, as discussed in the patent, dibenzoylmethane derivatives have the problem of photochemical instability, detracting from their effectiveness and requiring reapplication of sunscreens to skin. (See col. 1, lines 21-24.) In a direct attempt of solving this problem of photochemical instability of dibenzoylmethane derivatives, the inventors of the '195 patent discovered that the specific combination of dibenzoylmethane derivative and di/polyester of naphthalene dicarboxlic acid surprisingly increases the photo-instability of dibenzoylmethane. (See col. 1, line 65 to col. 2, line 4)

In contrast to this specificity of three combined active agents of Applicant's claim 1, the sunscreen formulation of the '195 merely includes a laundry list of potential adjunct ingredients to its active ingredients of dibenzoylmethane and di/polyester of naphthalene. These adjunct ingredients are included merely for good measure as generally-accepted additives, and *not* to achieve any particular goal other than for what already is known by one of skill in the art based on their inherent properties. (See col. 4, line 66 to col. 5, line 45.) Adjunct ingredients listed are vitamins, botanical extracts, antimicrobial agents, anti-inflammatory agents, skin smoothing agents, and antifungal agents, to name a few. (*Id.*) There-within, alkanolamines are mentioned at col. 5 lines 5; tyrosine, included as one potential example of the adjunct ingredient of an amino acid; is mentioned at col. 5, line 15; sulfur resorcinol at col. 5, line 6-7; and lipoic acid is mentioned at col. 5, line 14. While the required ingredients of Applicant's claim 1 can be found buried amidst a large amount and variety of other ingredients provided

generally in a laundry list, such mention-in-passing of each of these ingredients individually does not amount to a disclosure, nor a suggestion, of the *specific combination* of those three ingredients and the beneficial, surprising effects of that combination as achieved by Applicant's present invention. (*Id.*, While one of several therapeutic effects mentioned is "treat wrinkles acne, or to lighten the skin," at col. 5, line 3, there is no indication or teaching which of the several ingredients, alone or in combination, achieve that.) There is no teaching of which few, within the laundry list of the several, ingredients to combine and which to not include, to arrive at Applicant's invention, nor is there motivation to look to teachings regarding *adjunct* ingredients in a sunscreen whose active ingredient serves as a chemical block UV-A radiation to prevent it from reaching the skin (and preventing deleterious effects – wrinkles, burn, cancer – from ever occurring), rather than *acting directly upon* the skin, to find ingredients to be employed in a specific combination to act upon the skin. Further, there is no motivation to look to the teachings of adjunct ingredients in a composition whose main ingredient does *not* act upon the cells of the skin, in order to find a specific combination of adjunct ingredients that must act directly upon the cells skin in a method of treating an existing skin disease, acne, and preventing further acne from forming. Hence, for at least these reasons, the '195 patent fails to teach or suggest Applicants claims, overcoming the Examiner's rejection.

#### The '446 Patent

The '446 patent is directed to astringent composition having viscosity values of at least 5,000 centipose, containing astringent plus alcohol, and method of use, designed to overcome the problems of consistency and resulting difficulty in use and application of astringents typically having low viscosity values. (See col. 2, lines 14-30. ) To overcome these problems, the astringents of the '446 patent employ a relatively low alcohol concentration and increased viscosity values. (See col. 1, lines 32-34.) The astringents of '446 patent may further include adjunct ingredients that do not serve to address the problems the invention seeks to relieve. (See col. 2, line 61 to col. 3, line

67) These adjunct ingredients are included merely for good measure as generally-accepted additives, and *not* to achieve any particular goal other than for what already is known by one of skill in the art based on their inherent properties. Adjunct ingredients listed are sunscreen agents, botanical extracts, antimicrobial agents, anti-inflammatory agents, skin smoothing and soothing agents, and antifungal agents, to name a few. (*Id.*) Within the laundry list of adjunct ingredients, 2-dimethylaminoethanol) is mentioned at col. 3 lines 4; tyrosine, included as one potential example of the adjunct ingredient of an amino acid; is mentioned at col. 3, line 5; sulfur resorcinol at col.3, line 1; and lipoic acid (sulfur ingredient) is mentioned at col. 3, line 5. While these ingredients of Applicant's claim 1 can be found buried amidst a large amount and variety of other ingredients provided generally in a laundry list, such mention-in-passing of each of these ingredients individually does not amount to a disclosure, nor a suggestion, of the *specific combination* of those three ingredients and the beneficial, surprising affects of that combination as achieved by Applicant's present invention. (*Id.*, While one of several therapeutic effects of adjunct ingredients mentioned is to "treat wrinkles and/or acne, at col. 2, line 63, there is no indication or teaching which of the several ingredients, alone or in combination, achieve that.) There is no teaching of which few, within the laundry list of the several, ingredients to combine and which to not include, to arrive at Applicant's invention, nor is there motivation to look to teachings regarding *adjunct* ingredients in an astringent whose active ingredients serve to bind and tighten soft tissue and tone skin to find ingredients to be employed in a specific combination to act upon the skin in a method of treating an existing skin disease, acne, and preventing further acne from forming. Moreover, even if *arguendo*, there was a teaching of any of Applicant's ingredients, there would be motivation to combine teachings of an astringent and other alcohol-containing compositions as they are often too drying and harsh to be used on acne-affected skin and would not be referenced for insight in treatment of the skin disease of acne. (See Application at ¶ [0032], discussing alkanolamine compositions as advantageous in light of anti-inflammatory and anti-acne properties as conventional acne products, such as astringents cause redness and inflammation to

sensitive skin). Hence, for at least these reasons, the '446 patent fails to teach or suggest Applicants claims, overcoming the Examiner's rejection.

The '791 Patent

The '791 Patent is directed to a method of promoting metabolism, energy production and uptake and utilization of oxygen in the skin, by applying a combination of i) carnitine, or salt or ester thereof, and ii) pyruvic acids or salt or ester thereof. (See Abstract) Resultantly, skin firmness, elasticity, tone, texture and barrier function is improved. (See col. 1, lines 35-38.)

In contrast to this specificity of three combined active agents of Applicant's claim 1, the '791 patent merely includes a laundry list of potential adjunct ingredients to its active ingredients of carnitine and pyruvic acid. (See col. 4, lines 13-44.) These adjunct ingredients are included merely for good measure as generally-accepted additives, and *not* to achieve any particular goal other than for what already is known by one of skill in the art based on their inherent properties. Adjunct ingredients listed are sunscreen agents, botanical extracts, antimicrobial agents, anti-inflammatory agents, skin lightening agents, and antifungal agents, to name a few. (*Id.*) Within this laundry list of adjunct ingredients, 2-dimethylaminoethanol is mentioned at col. 4, line 24; tyrosine is mentioned at col. 4, line 55; sulfur resorcinol at col. 4, line 21; and lipoic acid is mentioned at col. 4, line 20. While these ingredients of Applicant's claim 1 can be found buried amidst a large amount and variety of other adjunct ingredients provided generally in a laundry list, such mention-in-passing of each of these ingredients individually does not amount to a disclosure, nor a suggestion, of the *specific combination* of those three ingredients and the beneficial, surprising affects of that combination as achieved by Applicant's present invention. (*Id.* While one of several therapeutic effects mentioned is "treat wrinkles acne, or to lighten the skin," at col. 4, lines 19-20, there is no indication or

teaching which of the several ingredients, alone or in combination, achieve that.) There is no teaching of which few, within the laundry list of the several, ingredients to combine and which to not include to arrive at Applicant's invention. Nor is there motivation to look to teachings regarding adjunct ingredients in a composition having carnitine-pyruvic acid active ingredients to promote oxygen consumption by the skin in order to find active ingredients to be employed in a *specific combination* of alkanolamines, tyrosine and a sulfur composition for use in methods of treating an existing *skin disease of acne*, and preventing further acne from forming. Hence, for at least these reasons, the '791 patent fails to teach or suggest Applicants claims, overcoming the Examiner's rejection.

#### Beneficial Results

Applicant's invention achieves a novel method of treating and preventing acne vulgaris manifested by the symptoms of pustule, papule, and comedone formation, minimizing the number and severity of lesions by employing a composition containing an alkanolamine having a specific formula, tyrosine, and a sulfur ingredient. A homogeneous skin complexion, and a simultaneously reduction of pore size, is achieved. The present invention results in evening out skin texture, minimizing scar formation, treating acneform scars left after resolution of the active phase, promoting clear and firm skin tone, and providing a healthier look as well as eliminating the social stigma when one suffers from acne.

The topical compositions employed in the methods of the present invention are further advantageous in that they ameliorate skin irritation caused by conventional acne formulations so that more efficacious therapies can be devised for individual patients based on their different medical needs, including therapies that combine different treatments. The beneficial results disclosed in Applicant's invention support a finding of patentability and nonobviousness over the cited references.

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Response to Official Action

Hence, for at least the aforementioned reasons, claims 1-15 are patentable and non-obvious over "the '195 patent", "the '446 patent", and "the '791 patent", as well as Applicant's prior two patents, whether considered alone or on combination.

Applicant respectfully asserts that the Examiner's rejection have been traversed by the aforementioned amendment and remarks. It is respectfully submitted that all of the pending claims are in order for allowance and early notice to that effect is respectfully requested.

Respectfully submitted,



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